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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,139	03/15/2004	Paul Haefner	GUID.609PA	9243

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
09/01/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/801,139	HAEFNER, PAUL	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *25,35,49-53,55-62,64 and 65* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *25,35,49-53,55-62,64 and 65* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner was unable to find support in the originally filed disclosure for a controller configured to separate cardiac electrical signals from non-cardiac electrical signals based on a comparison between the S1 heart sound the QRS complex. Page 31 of the disclosure appears to describe separating cardiac electrical signals from non-cardiac electrical signals, but this appears to be carried out by blind source separation or other separation technique *before* the comparison with hearts sounds is made.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 25, 35, 49-52, 55, 57, 59-62, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moberg et al. (US 5,496,361, hereinafter “Moberg”) in view of Mai et al. (US 6,643,548, hereinafter "Mai”).

6. In regards to claims 25 and 35, Moberg discloses a patient-implantable device (Fig. 18) comprising a housing (244); a plurality of electrodes for sensing electrical activity and features (250); electrical detection circuitry (252); an accelerometer for sensing heart movements (246); cardiac acceleration sensing circuitry (248); a controller (254) configured to correlate and discriminate between normal cardiac function and arrhythmia based on the electrical and acceleration signals (col. 18, line 49 to col. 19, line 17); communications circuitry (258) to telemeter the electrical and acceleration signals (col. 19, lines 12-17); and a patient external device comprising circuitry to receive the signals (col. 19, lines 12-17). Although Moberg discloses determining arrhythmia by manipulation of the electrical and acceleration signals over time and programmability of the controller (col. 18, lines 49-67); and that the two signals

are sent to the external telemetry unit (col. 19, lines 12-16), Moberg does not expressly and explicitly disclose that the correlation is carried out by opening a correlation window based a cardiac cycle feature fiducial point of the cardiac electrical signal to correlate heart sounds with cardiac cycle features of the same heart beat over a plurality of cycles, that the implantable and external units have a memory for saving the two signals, that the external device has a user interface for providing a visual output of the two signals, or that the acceleration is an "audio" signal. However, Mai teaches opening a correlation window for cardiac cycle fiducial points and identifying heart sounds within each window (col. 9, line 39 to col. 10, line 5) to provide the predictable results of accurately determining patient condition for modification of treatment. Furthermore, it is notorious in the art to provide both implantable and external units with a memory for saving various signals to provide the predictable results of computing with ubiquitous programmable microcontrollers and allowing monitoring of patient condition over time; external telemetry devices with user interfaces for providing a visual output of various signals to provide the predictable results of allowing a clinician to monitor patient condition; and monitoring heart accelerations as an "audio" signal to provide the predictable results of gathering frequencies of acceleration known to be useful in diagnosing various conditions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Moberg's invention by opening a correlation window for cardiac cycle fiducial points and identifying heart sounds within each window to provide the predictable results of accurately determining patient condition for modification of treatment; providing both implantable and external

units with a memory for saving various signals to provide the predictable results of computing with ubiquitous microcontrollers and allowing monitoring of patient condition over time; external telemetry devices with user interfaces for providing a visual output various signals to provide the predictable results of allowing a clinician to monitor patient condition; and monitoring heart accelerations as an “audio” signal to provide the predictable results of gathering frequencies of acceleration known to be useful in diagnosing various conditions.

7. In regards to claims 49, 51, 52, 59, 61, and 52, Moberg discloses diagnosing arrhythmia based on heart rate (col. 18, lines 33-34), with the acceleration signal used to confirm the diagnosis (col. 18, line 60 to col. 19, line 1). Since a high electrical-indicated rate is not confirmed as arrhythmia without acceleration signal confirmation, the system/method necessarily indicates the electrical-indicated rate as subject to "noise" (*i.e.*, not reflective of the “true” physiological rate).

8. In regards to claim 57, the sensor is on a lead (Figs. 19 and 20).

9. In regards to claims 50, 55, 60, 62, and 64, Moberg discloses the essential features of the claimed invention including diagnosing arrhythmia based on heart rate (col. 18, lines 33-34), with the acceleration signal used to confirm the diagnosis (col. 18, line 60 to col. 19, line 1), but does not expressly disclose diagnosing arrhythmia based on morphology of the electrical signal, correlating the S1 sounds with the QRS complexes, or detecting heart sounds based on a human input. However, Mai teaches diagnosing arrhythmia based on morphology of the electrical signal (col. 5, line 24) to

provide the predictable results of more reliable detection of heart conditions, correlating the S1 sounds with the QRS complexes (col. 9, line 39 to col. 10, line 5) to provide the predictable results of accurately determining patient condition for modification of treatment, and detecting heart sounds based on a human input (col. 9, lines 17-25) to provide the predictable results of consistent data acquisition. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Moberg's invention by diagnosing arrhythmia based on morphology of the electrical signal to provide the predictable results of more reliable detection of heart conditions, correlating the S1 sounds with the QRS complexes to provide the predictable results of accurately determining patient condition for modification of treatment, and detecting heart sounds based on a human input to provide the predictable results of consistent data acquisition.

10. Claims 56, 58, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moberg and Mai, as applied to claims 25 and 35 above, and further in view of Lee (US 7,035,684, hereinafter "Lee"). Moberg discloses the essential features of the claimed invention except for transmitting the indication of arrhythmia to the external device or a sensor, electrodes, and housing that form a rigid unitary structure. However, Lee teaches that is it known in the art to provide indications of arrhythmia to external devices (col. 12, lines 62 to col. 13, line 3) to provide the predictable result of sending information that is most useful to the clinician; and a sensor, electrodes, and housing that form a rigid unitary structure (Fig. 3) to provide the

predictable results of an easily implantable system. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Moberg's invention by providing indications of arrhythmia to external devices to provide the predictable result of sending information that is most useful to the clinician; and a sensor, electrodes, and housing that form a rigid unitary structure to provide the predictable results of an easily implantable system.

Allowable Subject Matter

11. Claim 53 appears to avoid the prior art, but remains rejected under section 112, paragraph 1, as outlined above.

Response to Arguments

12. Applicant's arguments filed 6/30/2011 have been fully considered but they are not persuasive. Applicant argued that Mai's disclosure of Figure 3 and column 9 drawn to determining that the patient is at rest and that the patient's heart rate is stable is a "teaching away" from using the windowing technique disclosed at Figure 4 and column 9, line 38 to column 10, line 26 to determine tachyarrhythmia, as claimed. The examiner incorporates the "response to arguments" of the previous office action and respectfully maintains that this disclosure by Mai is not a teaching away of combining the elements as set forth in the rejection above. The examiner's basis for this assertion is that these steps of determining that the patient is at rest (302) and that the heart rate is stable (Fig. 3) is not drawn to the efficacy or ability of the algorithm in Figure 4 to discern the various features (*e.g.*, R-wave, T-wave, and S1/S2 sounds), but is instead intended to ensure that the patient is in a consistent state every time that the

measurements are taken to allow for long-term tracking of heart failure (col. 2, lines 13-55, especially lines 43-48). In other words, these steps are taken to ensure that changes in the measured intervals are due to the improvement or deterioration of the patient's heart failure status and not due to variations in activity or exercise or the like. The examiner agrees and concedes that, if these steps were taken because the windowing technique would be unreliable or unworkable otherwise, this would be a "teaching away." However, it appears that the sole reason for these steps is to ensure consistent patient condition for determining long-term progression or regression of disease and not because doing otherwise would render the windowing technique unworkable. Although not expressly disclosed as being used for tachyarrhythmia diagnosis, Mai is not relied upon for this teaching, but is instead taught by Moberg. Moberg further teaches comparing an electrical ECG signal with a heart sound signal, but is silent as to how this comparison is made. Mai is relied upon for the very limited teaching of one such comparison means that includes the windowing technique as claimed, and the examiner respectfully maintains that this windowing technique is equally applicable to a tachyarrhythmic condition because a tachyarrhythmia waveform has R-waves, T-waves, S1 sounds, and S2 sounds -- these just occur at a faster rate than normal. Accordingly, the examiner maintains that because these four features are used in the windowing technique of Mai, that this windowing technique would be equally applicable to tachyarrhythmia detection as taught by Moberg. In short, Mai teaches at most that *he does not* use the windowing technique for tachyarrhythmia, and not that the technique *should not or could not* be used with tachyarrhythmia. Since there is no

factual evidence in the record to indicate that this windowing technique would be ineffective for tachyarrhythmia, the examiner respectfully maintains the previous grounds of rejection as set forth above. Again, the examiner is considering the passages of Mai cited by Applicant to not be a teaching away of using the windowing technique for tachyarrhythmia, but to be a teaching of acquiring signals at a consistent patient condition if determining heart failure progression over a long period of time -- an unrelated issue and not relied upon for the obviousness rejection.

Conclusion

13. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Primary Examiner, Art Unit 3762